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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,190	05/23/2006	Ezio Bombardelli	2503-1215	1808
<div>466 7590 01/02/2009</div> <div>YOUNG & THOMPSON</div> <div>209 Madison Street</div> <div>Suite 500</div> <div>ALEXANDRIA, VA 22314</div>				
EXAMINER				
MI, QIUWEN				
ART UNIT		PAPER NUMBER		
1655				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,190

Applicant(s)

BOMBARDELLI, EZIO

Examiner

QIUWEN MI

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-15, and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-15 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/08 has been entered.

Applicant's amendment in the reply filed on 9/2/08 is acknowledged, with the cancellation of Claims 2-5, and 16. Claims 1, 6-15, and 17-23 are pending. **Claims 1, 6-15, and 17-23 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Specification/Abstract Objections

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant is required to delete “The present invention relates to” on line 1 of the Abstract to be more clear and concise. The first letter of “compositions” in line 1 should be capitalized after the deletion.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11, 14, 15, 18, 19, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following Claims recite the limitation below. There is insufficient clear antecedent basis for the limitations in the claims.

Claims 7, 8, 18, and 19, line 2, “the β acids fraction”;

Claims 9, line 2, “the Hypericum sp. extract” (not consistent with “extracts” in claim 1);

Claim 10, line 2, “the phloroglucinols content”;

line 3, “the Hypericum perforatum extract”;

Claim 11, and 22, line 3, “the leaves”;

Claim 14, line 2, “the essential oil”;

Claim 15, line 2, “the affections”.

Claim 15, recite “the procyanidins are derived from a Vitis vinifera extract, a Camellia sinensis extract or from other edible plants containing **them**”, and it is not clear what Applicant

refers to by “them”. Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 8, 15, 18, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yaloveny Agric Ind (SU 1373398A), as evidenced by Nieuwenhuizen et al (US 2003/0064937)*, and Cooper et al (US 6,379,720)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/30/2008, repeated below. Applicants’ arguments filed have been fully considered but they are not deemed to be persuasive.

Yaloveny Agric Ind teaches a composition comprising grapes and extract of hops (see Abstract, the rejection is based on the Abstract))

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (columulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Yaloveny Agric Ind does not teach the claimed amount of the components in the composition.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the invention of Yaloveny Agric Ind since the composition of Yaloveny Agric Ind yielded beneficial results in food industry, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Distinctions of the present invention over the applied art references were set forth in the Amendment filed April 2, 2008. As has been noted,

YALOVENY AGRIC IND pertains to non-alcoholic drinks containing grape juice, wine grape seeds, wine-spirit extract of hops, lemon oil, carbon dioxide and water. YALOVENY AGRIC IND fails to disclose compositions for treatment of affections of the oral cavity and upper respiratory tract, such as are set forth in claims 1 and 15 of the present invention” (page 9, last paragraph).

This is not found persuasive. The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use for the treatment of the affections of the oral cavity and upper respiratory tract. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Claims 1, and 6-15, and 17-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Walker et al (US 5,474,774), Imaoka et al (JP 06179609 A), Barney et al (US 5,370,863), Van den Berghe (US 6,284,289), and Zou (CN 1421240), as evidenced by Gorenbein et al (US 5,955,102)*, Nieuwenhuizen et al (US 2003/0064937)*, Cooper et al (US 6,379,720)*, Ghosal (US 6,224,906)*, and Appendino et al (Oligomeric acylphloroglucinols from myrtle (*Myrtle communis*), Journal of Natural Products, 65 (3): 334-8, 2002)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/30/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Walker et al teach a composition for inhibiting the adhesion of *E. coli* bacteria to surfaces in a mammalian oral cavity (thus administering to a patient) (claim 1). Walker et al also teach that the invention comprises an extract made from plant material of plant species of the genus *Vaccinium*, and which is significantly enriched for an activity that interferes with adhesion of bacterial cells to surfaces (col 1, lines 42-46). Walker et al further teach that *V. myrtillis* (bilberry), etc are useful species (col 1, lines 63-67).

As evidenced by Gorenbein et al, bilberry extract (the same as *Vaccinium myrtillus*, col 3, lines 10-15) contains anthocyanoside.

Imaoka et al teach a composition with high antibacterial activity on oral bacteria (thus administering to a patient) comprising grape extract (see Abstract, the rejection is based on the Abstract).

As evidenced by Nieuwenhuizen et al (US 2003/0064937), grape contains procyanidins [0023, 0077].

Barney et al teach a composition for inhibiting undesirable gram positive microorganisms in the oral cavity bacteria proliferation (thus administering to a patient) comprising hops acids (col 1, lines 5-10).

As evidenced by Cooper et al, hops (the same as *Humulus lupulus*, col 1, lines 50-55) extract contains alpha acids (phloroglucinols), represented by humulone and its congeners (cohumulone, admululone) and beta acids, represented by lupulone and its congeners (colupulone, adlupulone) (col 1, lines 50-58).

Van den Berghe teaches a composition for treating cold sores (infection in oral cavity) (thus administering to a patient) comprising *Myrtus communis* and *Hypericum perforatum* (col 4, lines 14-22).

As evidenced by Ghosal, St. John's Wort extract (the same as *Hypericum perforatum*, col 1, lines 10-15) contains phloroglucinols and procyanidins (cols 2&3, Table 1).

As evidenced by Appendino et al, *Myrtus communis* contains phloroglucinols (see Abstract).

Zou teaches a composition for treating sore and swelling throat, acute pharyngitis, and acute laryngitis (oral cavity infection) (thus administering to a patient) comprising mint oil (see Abstract, the rejection is based on the Abstract).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating oral cavity infection. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for treating oral cavity infection.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating oral cavity infection. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie*

obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocrraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability for treating oral cavity infection, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results

are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Walker et al, Imaoka et al, Barney et al, Van den Berghe, and Zou since all of them teach compositions for oral cavity infection individually in the art. Since all the compositions yielded beneficial results in for oral cavity infection, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claim 11 is a product-by-process claim. It is deemed that the product disclosed by Van den Berghe is not materially differently from the claimed *Myrtus communis* extract, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Applicant argues that “Further, any unpatentability that could be alleged was fully rebutted by the unexpected results presented in the signed declaration of Ezio Bomabardelli filed May 7, 2008. The unexpected results were summarized by Tables 1 and 2 of the declaration, which are reproduced below” (page 10, 2nd paragraph). Applicant further argues that “The advantages of the invention are thus clear, and any prima facie unpatentability has thus been fully rebutted. At page 14 the Official Action asserted that the declaration was insufficient to overcome the rejection over claims 1 and 15 because these claims have been rejected under 35 USC §102(b) over YALOVENY AGRIC IND. However, the instant incorporation of claims has addressed this issue by incorporating into the independent claims subject matter rejected under 35 USC §103(a), which is rebutted by the unexpected results discussed above. These rejections are believed to be overcome, and withdrawal thereof is respectfully requested” (page 11, paragraphs 1-3).

This is not found persuasive. First of all, according to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte* The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant fails to present a side by side comparison between the claimed invention and the closest art to show the allegedly surprising results achieve any statistical significance. Secondly, independent claim 1 is also rejected under Yaloveny Agric Ind, and Applicant fails to present a side by side

comparison between the claimed invention and the closest art to show the allegedly surprising results.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

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/Michele Flood/

Primary Examiner, Art Unit 1655